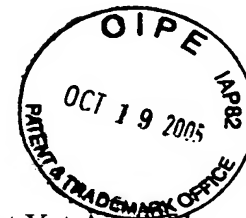


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Applicant:

Eduardo N. MITRANI et al

Serial No.: 10/519,838 ✓

Filed: January 12, 2005

For: METHOD AND DEVICES FOR INDUCING
BIOLOGICAL PROCESSES BY MICRO-
ORGANS

Examiner: Not Yet Available

Group Art Unit: Not Yet Available

Attorney
Docket: 28888Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450INFORMATION DISCLOSURE STATEMENT

Sir:

Enclosed is a PTO Form 1449 which lists citations which may be material to the patentability and examination of the above identified application. Also enclosed are copies of the references cited. These are submitted in compliance with the duty of disclosure defined in 37 CFR 1.56. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement under 37 CFR 1.56 is not to be construed as a representation that a search has been made, that additional matter which is material to the examination of this application does not exist, or that any or more of these citations constitutes prior art.

Respectfully submitted,

Martin Moynihan
Registration No. 40,338

Dated: October 6, 2005

PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/519,838
				Filing Date	January 12, 2005
				First Named Inventor	Eduardo N.MITRANI et al
				Art Unit	N/A
				Examiner Name	N/A
				Attorney Docket Number	28888
Sheet	1	of	5		
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US-3,984,533	05-5-1976	Uzgiris	
	2	US-3,996,345	07-7-1976	Ullman et al.	
	3	US-2002/0039786	04-4-2002	Reid et al.	
	4	US-4,369,788	01-25-1983	Goald	
	5	US-4,043,343	08-23-1977	Williams	
	6	US-4,498,778	02-12-1985	White	
	7	US-6,030,833	02-29-2000	Seebach et al.	
	8	US-2002/0012661	01-31-2002	Saito et al.	
	9	US-5,670,148	09-23-1997	Sherwin et al.	
	10	US-5,885,971	03-23-1999	German et al.	
	11	US-4,533,635	06-6-1985	Guédon born Saglier et al.	
	12	US-4,940,666	07-10-1990	Boyce et al.	
	13	US-5,282,859	01-1-1994	Eisenberg	
	14	US-5,292,655	08-8-1994	Wille Jr.	
	15	US-5,888,720	03-30-1999	Mitrani	
	16	US-4,353,888	10-12-1982	Sefton	
	17	US-4,391,909	05-5-1983	Lim	
	18	US-4,666,828	05-19-1987	Gusella	
	19	US-4,683,202	07-28-1987	Mullis	
	20	US-4,736,866	04-12-1988	Leder et al.	
	21	US-4,801,531	01-31-1989	Frossard	
	22	US-4,879,219	07-7-1989	Wands et al.	
	23	US-4,892,538	09-9-1990	Aebischer	
	24	US-5,106,627	04-21-1992	Aebischer	
	25	US-5,175,383	12-29-1992	Leder et al.	
	26	US-5,175,384	12-29-1992	Krimpenfort et al.	
	27	US-5,175,385	12-29-1992	Wagner et al.	
	28	US-5,192,659	09-9-1993	Simons	
	29	US-5,221,778	06-22-1993	Byrne et al.	
	30	US-5,272,057	12-21-1993	Smulson et al.	
	31	US-5,288,846	02-22-1994	Quertermous et al.	
	32	US-5,298,422	03-29-1994	Schwartz et al.	
	33	US-5,347,075	09-13-1994	Sorge	
	34	US-5,360,735	01-1-1994	Weinshank et al.	
	35	US-5,387,742	07-7-1995	Cordell	
	36	US-5,464,764	07-7-1995	Capecchi et al.	
	37	US-5,487,992	01-30-1996	Capecchi et al.	
	38	US-6,472,200	10-29-2002	Mitrani	
	39	US-4,883,666	11-28-1989	Sabel et al.	
	40	US-3,791,932	02-12-1974	Schuurs et al.	
	41	US-3,839,153	01-1-1974	Schuurs et al.	
	42	US-3,853,987	12-10-1974	Dreyer	
	43	US-3,935,074	01-27-1976	Rubinstein et al.	
	44	US-4,034,074	05-5-1977	Miles	

	45	US-4,098,876	04-4-1978	Piaso et al.	
	46	US-5,011,771	04-30-1991	Bellet et al.	
	47	US-5,281,521	01-25-1994	Trojanowski et al.	
	48	US-3,850,752	11-26-1974	Schuurs et al.	
	49	US-3,901,654	08-26-1975	Gross	
	50	US-5,888,720	03-30-1997	Mitrani	
	51	US-6,372,482	04-16-2002	Mitrani	
	52	US-3,867,517	02-18-1975	Ling	
	53	US-3,850,578	11-26-1974	McConnell et al.	
	54	US-2003/0157074	08-21-2003	Mitrani	
	55	US-2003/0152561	08-14-2003	Mitrani	
	56	US-2003/0152909	08-14-2003	Mitrani	
	57	US-2003/0152562	08-14-2003	Mitrani	
	58	US-6,001,647	12-14-1999	Peek et al.	
	59	US-6,303,136	10-16-2001	Li et al.	
	60	US-5,871,767	02-16-1999	Dionne et al.	
	61	US-5,861,313	01-19-1999	Pang et al.	
	62	US-3,734,851	05-22-1973	Matsumura	
	63	US-5,032,508	07-16-1991	Naughton et al.	
	64	US-4,835,102	05-30-1989	Bell et al.	
	65	US-4,888,291	12-19-1989	Barrandon et al.	
	66	US-4,798,885	01-17-1989	Mason et al.	
	67	US-5,387,576	07-7-1995	Mitrani	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Documents	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6
		Country Code ² Number ⁴ Kind Code ⁵ (if known)				
	68	PCT WO 01/00859	04-4-2001	Mitrani		
	69	PCT WO 97/27742	07-7-1997	Paik		
	70	PCT WO 96/30492	03-3-1996	Hu et al.		
	71	PCT WO 01/07098	01-1-2001	Mitrani		
	72	PCT WO 00/53795	09-14-2000	Katz et al.		
	73	PCT WO 01/23541	05-5-2001	Fodor et al.		
	74	PCT WO 97/15655	01-1-1997	Sittinger et al.		
	75	JP 11-76399	03-23-1999	Imai et al.		
	76	PCT WO 93/14200	07-22-1993	Wadworth et al.		
	77	PCT WO 94/06908	03-31-1994	Littman et al.		
	78	PCT WO 94/23049	10-13-1994	Gearhart et al.		
	79	PCT WO 94/28123	08-8-1994	Thompson et al.		
	80	PCT WO 99/06073	02-11-1999	Isner		
	81	PCT WO 98/15575	04-16-1998	Parmacek et al.		
	82	PCT WO 98/54301	03-3-1998	Mickle et al.		
	83	PCT WO 99/49807	07-7-1999	Mitrani		
	84	PCT WO 96/15225	05-23-1996	Mitrani		
	85	PCT WO 03/040686	05-15-2003	Pearlman et al.		
	86	PCT WO 03/049783	06-19-2003	Bellomo et al.		
	87	PCT WO 03/039382	05-15-2003	Pearlman et al.		
	88	PCT WO 03/049626	06-19-2003	Bellomo et al.		
	89	PCT WO 98/39035	09-11-1998	Herlyn et al.		
	90	PCT WO 91/12334	08-22-1991	Warren et al.		
	91	EP 0364306	04-18-1990	Chao		
	92	EP 0418035	03-3-1995	Kemp et al.		
	93	EP 0361957	04-4-1990	Bell et al.		
	94	EP 0271211	08-19-1992	Twardzik et al.		
	95	EP 0222491	05-20-1987	Mason et al.		
Examiner Signature					Date Considered	

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Sheet	3	Of	5	Attorney Docket Number	28888
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	96	Sugihara et al. "Reconstruction of the Skin in Three-Dimensional Collagen Gel Matrix Culture", In Vitro Cell Dev. Biol., 27A: 142-146, 1991.			
	97	Li et al. "Skin Toxicity Determined In Vitro by Three-Dimensional, Native-State Histoculture", Proc. Natl. Acad. Sci. USA, 88: 1908-1912, 1991.			
	98	Parenteau et al. "Epidermis Generated In Vitro: Practical Considerations and Applications", Journal of Cellular Biochemistry, 45: 245-251, 1991.			
	99	Norris "A Generous Contribution by Roche Dermatology Division of Hoffman-La Roche Inc. to the Endowment for the Journal Has Supported This Issue", The Journal of Investigative Dermatology, 95(4): 1, 1990.			
	100	Goldberg Alternative Methods in Toxicology Series, 7: 2 P., 1989. Preface.			
	101	Bell et al. "Testskin: A Hybrid Organism Covered by A Living Human Skin Equivalent Designed for Toxicity and Other Testing", Alternative Methods in Toxicology, 6(Chap.A3): 15, 1988.			
	102	Kao et al. "Skin Penetration and Metabolism of Topically Applied Chemicals in Six Mammalian Species, Including Man: An In Vitro Study With Benzo[a]pyrene and Testosterone", Toxicology and Applied Pharmacology, 81: 502-516, 1985.			
	103	Coulomb et al. "Interactions Dermo-Épidémiques et Pharmacologie Cutanée", Pathologie Biologie, 40(2): 139-146, 1992.			
	104	Parrish et al. "Minireview : Precision-Cut Tissue Slices: Applications in Pharmacology and Toxicology", Life Sciences, 57(21): 1887-1901, 1995.			
	105	Villeval et al. "Retrovirus-Mediated Transfer of the Erythropoietin Gene in Hematopoietic Cells Improves the Erythrocyte Phenotype in Murine β -Thalassemia", Blood, 84(3): 928-933, 1994.			
	106	Descamps et al. "Organoids Direct Systematic Expression of Erythropoietin in Mice", Gene Therapy, 2: 411-417, 1995.			
	107	Palù et al. "In Pursuit of New Developments for Gene Therapy of Human Diseases", J. Biotechnology, 68: 1-13, 1999.			
	108	Romano et al. "Gene Transfer Technology in Therapy: Current Applications and Future Goals", Stem Cell, 17: 191-202, 1999.			
	109	Kappel et al. "Regulating Gene Expression in Transgenic Animals", Current Opinion in Biology, 3: 548-553, 1992.			
	110	Mullins et al. "Transgenesis in Nonmurine Species", Hypertension, 22(4): 630-633, 1993.			
	111	Mullins et al. "Transgenesis in the Rat and Larger Mammals", J. Clin. Invest., 97(7): 1557-1560, 1996.			
	112	Houdebine "Production of Pharmaceutical Proteins From Transgenic Animals", J. Biotechnology, 34: 269-287, 1994.			
	113	Wall "Transgenic Livestock: Progress and Prospects for the Future", Transgenesis, 45: 57-68, 1996.			
	114	Sigmund "Viewpoint: Are Studies in Genetically Altered Mice Out of Control?", Arterioscler. Thromb. Vasc. Biol., 20: 1425-1429, 2000.			
	115	Niemann "Transgenic Farm Animals Get Off the Ground", Transgenic Research, 7: 73-75, 1998.			
	116	Crystal "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", Science, 270: 404-410, 1995.			
	117	Verma et al. "Gene Therapy - Promises, Problems and Prospects", Nature, 389: 239-242, 1997.			
	118	Deonarain "Ligand-Targeted Receptor-Mediated Vectors for Gene Delivery", Exp.			

		Opin. Ther. Patents, 8(1): 53-69, 1998.	
	119	Miller et al. "Targeted Vectors for Gene Therapy", FASEB J., 9: 190-199, 1995.	
	120	Eck et al. "Gene-Based Therapy", in: Goodman & Gilman's 'The Pharmacological Basis of Therapeutics', 9/E, Chap.5: 77-101, 1997.	
	121	Ledley "Pharmaceutical Approach to Somatic Gene Therapy", Pharm. Res., 13(11): 1595-1614, 1996.	
	122	Saadi et al. "Immunology of Xenotransplantation", Life Sciences, 62(5): 365-387, 1998.	
	123	Inverardi et al. "Cell Transplantation", in: 'Transplantation Biology: Cellular and Molecular Aspects', Raven Pub., Chap. 56, 1996.	
	124	Philpott et al. "Rat Hair Follicle Growth In Vivo", Br. J. Derm., 127: 600-607, 1992.	
	125	Lingna "Skin Toxicity Determined In Vitro by Three-Dimensional, Native-State Histoculture", Proc. Natl. Acad. Sci. USA, 88: 1908-1912, 1991.	
	126	Cameron "Recent Advances in Transgenic Technology", Molecular Biotechnology, 7: 253-265, 1997.	
	127	Eto et al. "Purification and Characterization of Erythroid Differentiation Factor (EDF) Isolated From Human Leukemia Cell Line THP-1", Biochemical and Biophysical Research Communications, 142(3): 1095-1103, 1987.	
	128	Chesnokova et al. "The Thymic Factor Tactivin Prevents ACTH From Stimulating Steroidogenesis by Mouse Adrenal Cells", Institute of Cytology and Genetics, USSR Academy of Science, 1990.	
	129	Burke et al. "Preparation of Clone Libraries in Yeast Artificial-Chromosome Vectors", Methods in Enzymology, 194: 251-270, 1991	
	130	Carey et al. "An Amino-Terminal Fragment of GAL4 Binds DNA as A Dimer", J. Mol. Biol., 209: 423-432, 1989.	
	131	Gale et al. "Growth Factors Acting Via Endothelial Cell-Specific Receptor Tyrosine Kinases: VEGF's, Angiopoietins, and Ephrins in Vascular Development", Genes and Development, 13: 1055-1066, 1999.	
	132	Huxley et al. "The Human HPRT Gene on A Yeast Artificial Chromosomes Is Functional When Transferred to Mouse Cells by Cell Fusion", Genomics, 9: 742-750, 1991.	
	133	Lamb et al. "Introduction and Expression of the 400 Kilobase Precursor Amyloid Protein Gene in Transgenic Mice", Nature Genetics, 5: 22-29, 1993.	
	134	Pearson et al. "Expression of the Human Beta-Amyloid Precursor Protein Gene From A Yeast Artificial Chromosome in Transgenic Mice.", Proc. Natl. Acad. Sci. USA, 90: 10578-10582, 1993.	
	135	Achim "In Vivo Model of HIV Infection of the Human Brain", Advances in Neuroimmunology, 4(3): 261-264, 1994.	
	136	Cress et al. "Critical Structural Elements of the VP16 Transcriptional Activation Domain", Science, 251: 87-90, 1991.	
	137	Davies et al. "Targeted Alterations in Yeast Artificial Chromosomes for Inter-Species Gene Transfer", Nucleic Acids Research, 20(11): 2693-2698, 1992.	
	138	Dickinson et al. "High Frequency Gene Targeting Using Insertional Vectors", Human Molecular Genetics, 2(8): 1299-1302, 1993.	
	139	Futterer et al. "Translation of A Polycistronic mRNA in the Presence of the Cauliflower Mosaic Virus Transactivator Protein", The EMBO Journal, 10: 3887-3896, 1991.	
	140	Jakobovits et al. "Germ-Line Transmission and Expression of A Human-Derived Yeast Artificial Chromosome", Nature, 362: 255-261, 1993.	
	141	Rothstein "Targeting, Disruption, Replacement, and Allele Rescue: Integrative DNA Transformation in Yeast", Methods in Enzymology", 194: 281-301, 1991.	
	142	Sadowski et al. "GAL4-VP16 Is An Unusually Potent Transcriptional Activator", Nature, 335: 563-564, 1988.	
	143	Schedl et al. "A Yeast Artificial Chromosome Covering the Tyrosinase Gene Confers Copy Number-Dependent Expression in Transgenic Mice", Nature, 362: 258-261, 1993.	
	144	Capecchi "Altering the Genome by Homologous Recombination", Science, 244: 1288-1292, 1989.	
	145	Iruela-Arispe et al. "Angiogenesis: A Dynamic Balance of Stimulators and Inhibitors", Thrombosis and Haemostasis, 78(1): 672-677, 1997.	
	146	Epstein et al. "Human Neural Xenografts: Progress in Developing An In-Vivo Model to Study Human Immunodeficiency Virus (HIV) and Human Cytomegalovirus	

		(HCMV) Infection", <i>Advances in Neuroimmunology</i> , 4(3): 257-260, 1994.	
	147	Sampson-Johannes et al. "Colonization of Human Lung Grafts in SCID-Hu Mice by Human Colon Carcinoma Cells", <i>Int. J. Cancer</i> , 65: 864-869, 1996.	
	148	Mansbridge et al. "Three-Dimensional Fibroblast Culture Implant for the Treatment of Diabetic Foot Ulcers: Metabolic Activity and Therapeutic Range", <i>Tissue Engineering</i> , 4(4): 403-414, 1998.	
	149	Freshney "Culture of Animal Cells, A Manual of Basic Technique: Three-Dimensional Culture System", 2nd Ed.(Chap.22): 297-307, 1987. Esp. P.302.	
	150	Kondo et al. "Long-Term Organ Culture of Rabbit Skin: Effect of EGF on Epidermal Structure In Vitro", <i>Journal of Investigative Dermatology</i> , 95(4): 397-402, 1990. P.397, Col.2.	
	151	Agren et al. "Human Fetal Pancreas: Culture and Function In Vitro", <i>Diabetes</i> , 29(Suppl.1): 64, 1980.	
	152	Choi et al. "TGF-Beta and Retinoic Acid: Regulators of Growth and Modifiers of Differentiation in Human Epidermal Cells", <i>Cell Regulation</i> , 1: 791-809, 1990.	
	153	Rheinwald "Serial Cultivation of Normal Human Epidermal Keratinocytes", <i>Methods in Cell Biology</i> , 21A: 229-254, 1980.	
	154	Pinkus "Examination of the Epidermis by the Strip Method of Removing Horny Layers", <i>J. of Invest. Derm.</i> : 383-386, 1951.	
	155	Soyer et al. "Extracorporeal Assist of Anhepatic Animals With Liver Slice Perfusion", <i>The American Journal of Surgery</i> , P.21-26, 1973.	
	156	Eiseman et al. "Prosthetics in Hepatic Assistance", <i>Transplantation Proceedings</i> , 3(4): 1519, 1971.	
	157	Gerlach "Hepatocyte Culture and Bioreactor Design for Liver Support Systems", in: 'Acute Liver Failure', Cambridge University Press, Chap.19, 1997.	
	158	Levine "The Growth of Adult Human Skin In Vitro", <i>Br. J. Derm.</i> , 86: 481, 1972.	
	159	Boyce et al. "Calcium-Regulated Differentiation of Normal Human Epidermal Keratinocytes in Chemically Defined Clonal Culture and Serum-Free Serial Culture", <i>Journ. of Investigative Dermatology</i> , 81: 33s-40s, 1983.	
	160	Boisseau et al. "Production of Epidermal Sheets in a Serum Free Culture System: A Further Appraisal of the Role of Extracellular Calcium", <i>Journal of Dermatological Science</i> , 3: 111-120, 1992.	
	161	Granov et al. "Extracorporeal Fixation of Liver Slices Onto the System of 'Artificial Kidney' Apparatus", <i>Pub Med.</i> , 116(3): 106-109, 1976.	
	162	Watson et al. "Sheep Vibrissa Dermal Papillae Induce Hair Follicle Formation in Heterotypic Skin Equivalents", <i>British Journal of Dermatology</i> , 131: 827-835, 1994.	
	163	Varani et al. "All-Trans Retinoic Acid and Extracellular Ca ²⁺ Differentially Influence Extracellular Matrix Production by Human Skin in Organ Culture", <i>American Journal of Pathology</i> , 142(6): 1813-1822, 1993.	
	164	Reynolds et al. "Cultured Dermal Papilla Cells Induce Follicle Formation and Hair Growth by Transdifferentiation of An Adult Epidermis", <i>Development</i> , 115: 587-593, 1992.	
	165	Gurdon "The Generation of Diversity and Pattern in Animal Development", <i>Cell</i> , 68: 185-199, 1992.	

Signature		Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹. Applicant's unique citation designation number (optional). ². Applicant is to place a check mark here if English language Translation is attached.

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